

**REMARKS**

Applicant's undersigned attorney thanks the Examiner for his comments provided in the 02 February 2010 Office Action and the interview conducted on 06 May 2010. Applicant respectfully requests reconsideration of this patent application, particularly in view of the above Amendment addressing the criticality of halting probiotic activity in the composition and the following remarks.

Applicant's claimed invention is a composition which includes at least one DHLA-producing probiotic organism, R-lipoic acid, at least one nutritive agent, dihydrolipoic acid (DHLA), and an effective amount of an agent which halts probiotic activity.

**Amendments to the Claims**

Claims 4-22 and 24-38 are pending with Claims 13-19 withdrawn. Claims 4-12, 20-22, and 24-38 have been examined with no claims allowed.

Claims 4, 21, and 24 have been amended to recite compositions including at least one probiotic organism, R-lipoic acid, at least one nutritive agent, dihydrolipoic acid, and an effective amount of a probiotic halting agent to halt probiotic activity in the composition. Support is found on page 6, lines 20-27.

Claims 4, 13, 16, and 21 have been amended to delete the term "naturally derived."

Claim 26 has been amended to recite that the probiotic activity halting agent comprises ethanol.

Claims 27-38 have been cancelled.

No new matter has been added by this Amendment. No additional claim fees are believed to be due because the number of claims currently pending does not exceed the number previously paid for. However, should any fees be required (to maintain the pendency of this application or to timely enter this responsive paper into the file of the above-captioned application) or an overpayment of fees made, the Commissioner is hereby authorized to debit or credit our Deposit Account No. 50-3394, as necessary.

**Interview Summary**

During the interview conducted on 06 May 2010, Applicant's undersigned attorney discussed with the Examiner the rejection of Claims 4-12, 20-22, and 24-38 in view of the cited references, the use of an agent, such as ethanol, in an amount effective to halt probiotic activity, and the

limitation of product-by process claims were discussed. No decision regarding the allowability of the proposed claims was made.

Applicant's undersigned attorney further thanks the Examiner for his comments regarding certain language presented in the Claims submitted in connection with the Request for Continued Examination and comments with regard to the Declaration of Dr. Robert J. Marshall submitted on 14 August 2009. Applicant's undersigned attorney has duly taken into consideration these comments when preparing the current amendments.

### **Claim Rejections – 35 USC §103**

#### **I. Hastings in view of Niggemann and Biewenga, and in further view of Hermann**

The rejection of Claims 4-10, 20-22, 25-27, and 29-35 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,368,617 to Hastings et al. in view of German Patent DE 19730538 to Niggemann, Biewenga et al. (Gen. Pharmac, 1997) and in further view of Hermann et al (European Journal of Pharmaceutical Sciences, 1996) in light of support from Dunne et al. and Mercenier et al. is respectfully traversed.

Applicant's invention as recited in amended Claims 4, 21, and 27 is a composition including at least one probiotic organism, R-lipoic acid, at least one nutritive agent, dihydrolipoic acid, and an effective amount of an agent which halts probiotic activity. None of the references of record disclose or suggest such a combination.

Generally, as would be understood by a person of ordinary skill in the art, live microorganisms are included in dietary supplements to confer a health benefit to the host. Hastings, Dunne, and Mercenier all teach or disclose that live probiotic organisms can be ingested by an individual to his/her benefit. Indeed, Hastings discloses dietary supplements which include probiotic organisms for promoting healthy hormone balance and reducing the effects of aging in adult human subjects. In particular, Hastings discloses that a probiotic blend of *Bifidobacterium bifidum* and *Lactobacillus acidophilus*, and the fructo-oligosaccharides, are included in dietary supplement to promote intestinal health by increasing and maintaining intestinal flora (Col. 4, line 66 – Col. 5, line 3).

Niggemann discloses fermented beverages (e.g., kefir) for human consumption including at least two types of probiotic organisms, such as Aerobacter, *Bifidobacterium*, and/or *Lactobacillus* (Abstract). Additionally, Niggemann states that ethanol can be used to increase or extend the beverage shelf life of such beverages (page 2, ¶ 7 of the machine translation).

However, Niggemann also discloses that the presence of higher levels of ethanol (i.e., greater than 0.1% vol) is undesirable due to ethanol's affect on the smell and flavor of the beverage and the unsuitability of such beverages for infants, children and people with alcohol problems (page 3, ¶ 5 of the machine translation). Further Niggemann, similar to Hastings, discloses that the benefit of ingesting fermented beverages such as Kefir is found in the living bacterial cultures (page 1, ¶ 7 of the machine translation) and that the ethanol content of currently available fermented beverages forbids a quantitatively sufficient daily microorganism supply (page 2, ¶ 7 of the machine translation). Finally, Niggemann specifically states that the intent of the invention is to minimize the presence of ethanol in fermented beverages such as kefir to a level below 0.1% vol so as to eliminate the above disadvantages (Abstract and page 4, ¶¶ 2-3 of the machine translation). effective amount and "activity" are broad so I have at least something inside this breath

Accordingly Niggemann, similar to Hastings, also teaches away from compositions comprising an agent in an amount which is effective to halt probiotic activity because such an amount would prevent the probiotic organisms from increasing or maintaining intestinal flora.

Thus, there is no motivation for a person of ordinary skill in the art to modify the compositions disclosed in Hastings to include an effective amount of probiotic activity halting agent to halt probiotic activity in the compositions, because such a modification would render the probiotic organisms in the compositions of Hastings, alone or as modified by Niggemann, Biewenga, and/or Hermann, unsuitable for their intended purpose, i.e., to reduce the effects of aging such as by promoting intestinal health of a host. Accordingly, Applicant respectfully submits that Hastings in view of Niggemann and Biewenga and in further view of Hermann in light of support from Dunne and Mercenier does not disclose or suggest a composition including an agent in an amount effect to halt probiotic activity.

For at least the reasons above, Claims 4 and 21 as amended are patentable over Hastings in view of Niggemann, Biewenga, and Hermann. Claims 27 and 29-35 have been cancelled. Because Claims 5-10, 20, 25 and 26 depend from Claim 4, and Claim 22 depends from Claim 21, these claims are also patentable over Hastings in view of Niggemann, Biewenga and Hermann. Accordingly, reconsideration and withdrawal of this rejection with respect to Claims 4-10, 20-22, 25-27, and 29-35 are respectfully requested.

**II. Hastings in view of Niggemann, Biewenga, and Hermann and in further view of Reddy**

The rejection of Claims 4-12, 20-22, and 24-38 under 35 U.S.C. § 103(a) as unpatentable over Hastings in view of Niggemann, Biewenga, and Hermann in light of Dunne and Mercenier and in further view of U.S. Patent 6,080,401 to Reddy et al. is respectfully traversed.

As discussed above, Hastings, alone or as modified by Niggemann, Biewenga, and/or Hermann, does not disclose or suggest a composition including an effective amount of an agent which halts probiotic activity. Thus, Claims 4, 21, and 27 as amended are believed to be patentable. Additionally, because Claims 24, 27, and 36 as amended also recite compositions including an effective amount of an agent which halts probiotic activity, these claims are also believed to be patentable for the same reasons.

Reddy teaches compositions that include a probiotic blend of *Bifidobacterium* and *Lactobacillus* (Col. 9, lines 33-44) and which can also contain *Curcuma longa* (Col. 8, line 5). Reddy, however, does not overcome the deficiencies of Hastings in view of Niggemann, Biewenga, and Hermann. In fact Reddy further teaches away from the composition recited in amended Claims 4, 21, and 24. Specifically, Reddy requires that the compositions disclosed therein include viable probiotic organisms and that such compositions be free of substances which are substantially inhibitory to the viability of the probiotic organisms for it is the activity of the probiotic organisms that enhances the efficacy of the drug with which it is combined (see, e.g., Col. 6, lines 30-33). Thus, Reddy teaches away from the combination of a probiotic organism, R-lipoic acid, turmeric rhizome, and an effective amount of an agent which halts probiotic activity as recited in Claims 4, 21, and 24.

For at least these reasons, Applicant respectfully submits that Claims 4, 21, and 24 are patentable over Hastings in view of Niggemann, Biewenga, and Hermann and in further view of Reddy. Claims 27-38 have been cancelled. Because Claims 5-12, 20, 25 and 26 depend from Claim 4 and Claim 22 depends from Claim 21, these claims are also believed to be patentable. Accordingly, reconsideration and withdrawal of this rejection as applied to Claims 4-12, 20-22, and 24-38 are respectfully requested.

**Conclusion**

Applicant believes that the application is now in condition for allowance. If the Examiner feels that any issues remain regarding this application, then Applicant's undersigned attorney respectfully requests a telephone interview with the Examiner to discuss these issues. The undersigned can be reached at (312) 327-3327.

Respectfully submitted,

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